NEWS RELEASE

U.S. FDA Accepts sBLA for ENFLONSIA™ (clesrovimab-cfor) to Update its Respiratory Syncytial Virus (RSV) Lower Respiratory Tract Disease Indication to Include Children Under Two Years at Increased Risk for Severe RSV for Their Second Season

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EMA also accepts application for the same population for ENFLONSIA based on results from the Phase 3 SMART trial

If approved, children under two years of age at increased risk for severe RSV disease will be eligible to receive an additional dose of ENFLONSIA for their second RSV season

RAHWAY, N.J.--(BUSINESS WIRE)-- Merck (NYSE: MRK), known as MSD outside of the United States and Canada, announced today that the U.S. Food and Drug Administration (FDA) has accepted a supplemental Biologics License Application (sBLA) for ENFLONSIA™ (clesrovimab-cfor) to expand its indication to include prevention of respiratory syncytial virus (RSV) lower respiratory tract disease (LRTD) in children under two years of age at increased risk for severe RSV disease through their second RSV season. The FDA has set a Prescription Drug User Fee Act (PDUFA), or target action, date of March 22, 2027.

In July 2026, the European Medicines Agency (EMA) accepted the application to expand marketing authorization for ENFLONSIA in the European Union (EU) for the same population.

ENFLONSIA was **approved by the U.S. FDA** in June 2025 and by the **European Commission** in April 2026 for the

prevention of RSV LRTD in infants born during or entering their first RSV season. ENFLONSIA is the first and only preventive option against RSV LRTD administered to infants without the need for weight-based dosing.

“For some children, the potentially serious impact of RSV does not stop after their first RSV season,” said Dr. Macaya Douoguih, vice president, Therapeutic Area Head, Global Clinical Development, Merck Research Laboratories. “The recent FDA and EMA regulatory filings represent important opportunities to help expand protection with ENFLONSIA for vulnerable children under two years of age during their second RSV season – potentially further reducing the significant burden of RSV on families and health care systems.”

Even with protection during their first RSV season, certain children – including those born with chronic lung disease, congenital heart disease or early or moderate preterm birth with certain risk conditions – remain vulnerable to severe RSV disease during their second RSV season.

Both the U.S. and EU applications are supported by data from the **Phase 3 SMART trial** (MK-1654-007), which were **presented** at RSVVW’26, the 9th conference of the Respiratory Syncytial Virus Foundation (ReSViNET), in February 2026 and published in the **New England Journal of Medicine** in September 2025 (interim RSV season 1 results) and **JAMA Pediatrics** in July 2026 (full results).

ENFLONSIA is approved in more than 40 countries worldwide, including the **United States**, Canada, the **European Union**, China and Japan, for use in infants during their first RSV season. Regulatory filings are underway for approval in additional countries globally, as well as for indication expansion where already approved.

About the Phase 3 SMART Trial

The SMART trial (MK-1654-007) (**NCT04938830**) was a Phase 3, randomized, partially-blind, palivizumab-controlled, multicenter study to evaluate the safety, efficacy and pharmacokinetics of ENFLONSIA in infants and children at increased risk for severe RSV disease over two RSV seasons. The trial enrolled early (<29 weeks gestational age [GA]) or moderate preterm infants (≥29 to ≤35 weeks GA) and infants with chronic lung disease (CLD) of prematurity or congenital heart disease (CHD) of any GA.

In RSV season 1, participants were randomized 1:1 to receive either a 105 mg dose of ENFLONSIA (n=502) or monthly palivizumab (n=501) by intramuscular (IM) injection. In RSV season 2, eligible participants (children under 2 years of age with CLD, CHD or early or moderate preterm birth with certain risk conditions) received an additional open-label 210 mg dose of ENFLONSIA by IM injection (n=276, of whom 138 received ENFLONSIA and 138 received palivizumab in RSV season 1). Nearly all participants (99%) who received ENFLONSIA in RSV season 2 had CLD (n=229) or CHD (n=43).

About RSV Globally

Respiratory syncytial virus (RSV) is a contagious virus that causes widespread seasonal infections and can lead to serious respiratory conditions such as bronchiolitis and pneumonia. As a leading cause of hospitalization among infants globally, there is persisting unmet need for RSV preventive options for both healthy and high-risk infants during their first RSV season as well as for children at increased risk for severe RSV disease through their second RSV season. RSV season is the time of year when RSV infections are most common, usually occurring autumn through spring of the next year in temperate climates. Timing and severity in a given community or region can vary year to year.

About ENFLONSIA™ (clesrovimab-cfor) in the U.S.

ENFLONSIA is Merck's **FDA-approved** extended half-life monoclonal antibody (mAb) indicated for passive immunization for the prevention of respiratory syncytial virus (RSV) lower respiratory tract disease in newborns and infants who are born during or entering their first RSV season. ENFLONSIA is administered using the same dose regardless of weight (105 mg/0.7 mL in a prefilled syringe) and is designed to provide direct, rapid and durable protection through 5 months, a typical RSV season. For infants born during the RSV season, ENFLONSIA is to be administered within the first week of life. For infants born outside of the RSV season, ENFLONSIA should be administered shortly before the RSV season begins. For infants undergoing cardiac surgery with cardiopulmonary bypass during or entering their first RSV season, an additional 105 mg dose is recommended as soon as the infant is stable after surgery. ENFLONSIA has a 30-month shelf life.

Selected Safety Information for ENFLONSIA™ (clesrovimab-cfor) in the U.S.

Do not administer ENFLONSIA to infants with a history of serious hypersensitivity reactions, including anaphylaxis, to any component of ENFLONSIA.

Serious hypersensitivity reactions, including anaphylaxis, have been observed with other human immunoglobulin G1 (IgG1) monoclonal antibodies. If signs or symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, initiate appropriate medications and/or supportive therapy.

ENFLONSIA may interfere with some immunologically-based RSV diagnostic assays (i.e., rapid antigen tests) as observed in laboratory studies. Confirmation using a reverse transcriptase polymerase chain reaction (RT-PCR) assay is recommended when rapid antigen assay results are negative and clinical observations are consistent with RSV infection.

The most common adverse reactions were injection-site erythema (3.8%), injection-site swelling (2.7%) and rash (2.3%).

About Merck

At Merck, known as MSD outside of the United States and Canada, we are unified around our purpose: We use the

power of leading-edge science to save and improve lives around the world. For more than 130 years, we have brought hope to humanity through the development of important medicines and vaccines. We aspire to be the premier research-intensive biopharmaceutical company in the world – and today, we are at the forefront of research to deliver innovative health solutions that advance the prevention and treatment of diseases in people and animals. We foster a diverse and inclusive global workforce and operate responsibly every day to enable a safe, sustainable and healthy future for all people and communities. For more information, visit **www.merck.com** and connect with us on **X (formerly Twitter)**, **Facebook**, **Instagram**, **YouTube** and **LinkedIn**.

Forward-Looking Statement of Merck & Co., Inc., Rahway, N.J., USA

This news release of Merck & Co., Inc., Rahway, N.J., USA (the "company") includes "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of the company's management and are subject to significant risks and uncertainties. There can be no guarantees with respect to pipeline candidates that the candidates will receive the necessary regulatory approvals or that they will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the company's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of the company's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

The company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in the company's Annual Report on Form 10-K for the year ended December 31, 2025 and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site (**www.sec.gov**).

Please see Prescribing Information for ENFLONSIA (clesrovimab-cfor) at **https://www.merck.com/product/usa/pi_circulars/e/enflonsia/enflonsia_pi.pdf** and Patient Information/Medication Guide for ENFLONSIA at **https://www.merck.com/product/usa/pi_circulars/e/enflonsia/enflonsia_ppi.pdf**.

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